## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

| TALECRIS BIOTHERAPEUTICS, INC. and BAYER HEALTHCARE LLC,                                   |   |
|--|---|
| Plaintiffs,  v.  BAXTER INTERNATIONAL INC. and BAXTER HEALTHCARE CORPORATION,  Defendants. | Civil Action No.: 05-349-GMS  Jury Trial Demanded |
| BAXTER HEALTHCARE CORPORATION,  Counterclaimant,  v.                                       |   |
| TALECRIS BIOTHERAPEUTICS, INC. and BAYER HEALTHCARE LLC,                                   |   |
| Counterdefendants.   |   |

# BAXTER INTERNATIONAL, INC. AND BAXTER HEALTHCARE CORPORATION'S IDENTIFICATION OF PRIOR ART PURSUANT TO 35 U.S.C. SECTION 282

In accordance with 35 U.S.C. Section 282, Defendants Baxter International, Inc. and Baxter Healthcare Corporation ("Baxter") hereby identify the following prior art upon which it will rely in this case. This identification of prior art is based on the evidence produced during discovery and Plaintiffs Talecris Biotherapeutics, Inc. and Bayer Healthcare LLC's current contentions. Baxter reserves the right to supplement this identification in response to new information, contentions or defenses not currently known to Baxter.

- 1. U.S. Patent No. 4,396,608 (Tenold) (1983)
- 2. U.S. Patent No. 4,540,573 (Neurath, et al.) (1985)

- 3. U.S. Patent No. 4,762,714 (Mitra) (1988)
- 4. U.S. Patent No. 5,256,771 (Tsay) (1993)
- 5. EP 0523404A1 (Dobkin) (1992)
- 6. EP 525 502 A1 (Gehringer) (1992)
- Barandun, S., et al., "Intravenous Administration of Human γ-Globulin," Vox
   Sang. 7:157-174 (1962)
- 8. Biesert, et al., "Virus validation of a new polyvalent intravenous immunoglobulin (Octagam)," Vox Sang. 67:S2 (July 1994); Abstract 0726
- 9. Edwards, et. al., "Tri(n-Butyl) Phosphate/Detergent Treatment of Licensed

  Therapeutic and Experimental Blood Derivatives," Vox Sang. 52:53-59

  (1987)
- 10. Eriksson, et al., "Virus validation of plasma-derived products produced by Pharmacia, with particular reference to immunoglobulins," Blood

  Coagulation and Fibrinolysis, 5(3):S37-S44 (1994)
- Hämäläinen et. al., "Virus Inactivation during Intravenous Immunoglobulin Production," Vox Sang. 63:6-11 (1992)
- 12. Louie, et al., "Inactivation of Hepatitis C Virus in Low pH Intravenous Immunoglobulin," Biologicals 22:13-19 (1994)
- 13. Malagras, J., et al., "Mesure de l'activité anti-complémentaire, des préparations de gamma-globulines injectables par voie intra-veineuse", Revue Française de Transfusion T. XHL. N° 2. (1970)
- Ng, et. al., "Process-Scale Purification of Immunoglobulin M Concentrate,"
   Vox Sang. 65:81-86 (1993)

- 15. Octagam EU Brochure (February 1995) (BXTR148771 BXTR148786)
- 16. Octagam Israeli Brochure (1994) (BXTR159709 BXTR159712)
- 17. Piet, et al., "The use of tri(n-butyl) phosphate detergent mixtures to inactivate hepatitis viruses and human immunodeficiency virus in plasma and plasma's subsequent fractionation," *Transfusion*, 30(7) 591-598 (1990)
- 18. Prince, et al., "Failure of a human immunodeficiency virus (HIV) immune globulin to protect chimpanzees against experimental challenge with HIV," Proc. Natl. Acad. Sci. USA, 85:6944-6948 (1988)
- 19. Rousell R., *et al.* "Anticomplementary Activity and the Safety of Intravenous Immunogobulin Clinical Therapeutics" Vol 11:143-150 (1989)
- Uemera, Y., et al., "Inactivation and Elimination of Viruses during
   Preparation of Human Intravenous Immunoglobulin," Vox Sang. 67:246-254
   (1994)
- 21. Venoglobulin-S product insert (1992) (BXTR096247 BXTR096248)
- Wickerhauser, M. and Hao, Y., "Large Scale Preparation of Macroglobulins,"
   Vox Sang. 23:119-125 (1972)
- 23. Yang, Y.H., et al., "Antibody Fc Functional Activity of Intravenous Immunoglobulin Preparations Treated with Solvent-Detergent for Virus Inactivation," Vox Sang. 67:337-344 (1994)

By:

### POTTER ANDERSON & CORROON LLP

### OF COUNSEL:

James G. Gilliland, Jr.
Susan M. Spaeth
Anne M. Rogaski
TOWNSEND AND TOWNSEND AND
CREW LLP
379 Lytton Avenue
Palo Alto, California 94301
(650) 326-2400

Dated: June 8, 2007

800306

Philip A. Rovner (#3215)

Hercules Plaza P.O. Box 951

Wilmington, Delaware 19899-0951

(302) 984-6000

Email: provner@potteranderson.com

Attorneys for Defendant Baxter International Inc. and Defendant/Counterclaimant Baxter Healthcare Corporation

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

### **CERTIFICATE OF SERVICE**

I, Philip A. Rovner, hereby certify that on June 8, 2007, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

#### BY HAND DELIVERY AND E-MAIL

Jeffrey B. Bove, Esq.
Mary W. Bourke, Esq.
Mark E. Freeman, Esq.
Jaclyn Mason, Esq.
Donna Hallowell
Connolly Bove Lodge & Hutz LLP
1007 N. Orange Street
P. O. Box 2207
Wilmington, DE 19899-2207
jbove@cblh.com, mbourke@cblh.com
mfreeman@cblh.com, jmason@cblh.com
dhallowell@cblh.com; cjeffers@cblh.com;
dhammond@cblh.com; mlambert@cblh.com

### **BY EMAIL**

Dana K. Hammond, Esq.
M. Curt Lambert, Esq.
Connolly Bove Lodge & Hutz LLP
1007 N. Orange Street
Wilmington, DE 19899
jhammond@cblh.com; mlambert@cblh.com

Christopher E. Jeffers, Esq. Connolly Bove Lodge & Hutz LLP 1990 M. Street, NW Washington, DC 20036-3425 cjeffers@cblh.com

I hereby certify that on June 8, 2007 I have sent by E-mail and Federal Express the foregoing document to the following non-registered participants:

Bradford J. Badke, Esq.
Gabrielle Ciuffreda, Esq.
Ropes & Gray LLP
1211 Avenue of the Americas
New York, NY 10036-8704
bradford.badke@ropesgray.com; gabrielle.ciuffreda@ropesgray.com

/s/ Philip A. Rovner

Philip A. Rovner (#3215)
Potter Anderson & Corroon LLP
Hercules Plaza
P. O. Box 951
Wilmington, DE 19899
(302) 984-6000
provner@potteranderson.com